UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL DOCKET NO. 1456 Master File No. 01-CV-12257 Subcategory Case No. 06-CV-11337
THIS DOCUMENT RELATES TO:	)	Judge Patti B. Saris
U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al., No. 06-CV-11337-PBS *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey, Inc., et al.,* No. 05-CV-11084-PBS; and *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp. et al.,* No. 07-CV-10248-PBS	)	Magistrate Judge Marianne B. Bowler

DEFENDANTS' COMBINED SUR-REPLY TO THE
UNITED STATES' MOTIONS FOR PARTIAL SUMMARY JUDGMENT

The voluminous briefing on DOJ's motions for summary judgment proves Defendants' central point: disputed issues of fact remain on every element of DOJ's claims. Overwhelming evidence shows that state and federal officials understood and expected that the compendia-published AWPs for generic drugs – and the Subject Drugs in particular – were far higher than market prices and were not a reliable indicator of acquisition cost. Evidence also shows that officials nevertheless chose to use these AWPs in their reimbursement formulas for a variety of policy reasons divorced from any supposed fraud. Because DOJ cannot contest this evidence head on, it instead points to isolated snippets in the record that allegedly suggest the Medicare and Medicaid programs had different expectations and intentions. At most, this demonstrates disputes of material fact that a jury must resolve. DOJ's motions should be denied.

ARGUMENT

I. ISSUES OF FACT REGARDING EXPECTATIONS PRECLUDE SUMMARY JUDGMENT FOR DOJ.

This Court's rulings in AWP litigation have consistently focused on what plaintiff-payors expected about the relationship between published prices and acquisition cost for the drugs at issue. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 39-41, 76-78, 86-92 (D. Mass. 2007) (basing findings of fact on a 30% "expectations yardstick" for single-source drugs); *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 150-52 (D. Mass. 2008) (addressing Medicaid officials' expectations regarding published WACs).

The First Circuit's recent decisions in *In re Pharm. Indus. Average Wholesale Price Litig.* No. 08-1056, __ F.3d. __, slip op. (1st Cir. Sept. 23, 2009) ("*Astra-Zeneca*") and *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 08-1002, __ F.3d __, slip op. (1st Cir. Sept. 29, 2009) ("*J&J*"), affirm the importance of a factual record on expectations. In *Astra-Zeneca*, the First Circuit affirmed this Court because it found the *evidentiary record* supported a finding that

"spreads exceeded industry expectations." *Astra-Zeneca*, slip. op. at 31; *id.* at 46-60. In *J&J*, the First Circuit remanded for further proceedings because summary judgment was not warranted without a factual record regarding what plaintiffs expected about spreads. *J&J*, slip op. at 7-9.

Here, DOJ's motions for summary judgment do not rely on any evidence regarding what relevant officials expected about spreads for the generic drugs at issue. This lack of evidence on a central proposition dooms DOJ's motions. The First Circuit held in *J&J* that it was improper in Track 1 to apply to Class 1 (absent fact-findings by the court or jury) the same 30% speed-limit applied to Classes 2 and 3. DOJ certainly cannot seek to import that same yardstick (or a 25% "mark-up")[1] to these cases, which involve different payors and a different class of drugs. To put it mildly, the expectations here are nothing like what this Court found in Track 1.

A 25% or 30% speed-limit has no place in a case involving generics. Dr. Hartman's 30% speed-limit "focused on breakthrough innovator drugs," not generics. *Astra-Zeneca*, slip op. at 56; *id.* at 49, n.18 ("Notably, Dr. Hartman's submissions assumed a 30% baseline spread for single-source drugs during periods where the drugs were without competition . . . ."). In contrast, the record here shows a widespread understanding (including by DOJ's own expert) that compendia AWPs for generics were not reliable indicators of acquisition cost in any way, shape, or form. (C. Mem. at 2-3, 8-9; C. SOAF ¶¶ 1-3, 9, 11, 13.)[2] As summarized in a 1994 Illinois document, AWP was known to be "virtually meaningless as a real number, particularly for multi-source drugs." (C. SOAF ¶ 1(j).) Large percentage (but low dollar) spreads were hardly unique to Defendants: the OIG graphically demonstrated that, in stark contrast to single-source drugs,

[1] DOJ's 25% "mark-up" (Mstr. Dkt. No. 5492) is not an "expectations yardstick." DOJ's expert added the 25% to account what First Databank added to certain manufacturers' prices. (Mstr. Dkt. No. 6189 at ¶ 84.)

[2] Citations are as follows: "Reply" = Dkt. No. 459; "C. Mem." = Dkt. No. 409; "C. SOAF" = Mstr. Dkt. No. 6447; "Abt. Opp." = Dkt. No. 415; "AF" = Dkt. No. 423; "Dey Opp." = Dkt. No. 422; "Rox. Opp." = Dkt. No. 410. Unless otherwise noted, Dkt. Nos. are to Subcategory Dkt. 06-CV-11337-PBS.

the vast majority of the 5,575 invoices it collected in 1999 for generics covered by a FUL sold at discounts of *at least 85%* off AWP (a "spread" of 566%). (*See* charts at C. Mem. at 2.)

As this Court did in Track 1, the fact-finders here will need to review *the evidence* on expectations in order to determine liability. They will find extensive evidence that relevant officials *did* expect "'huge spreads . . . for the drugs on trial.'" *Astra-Zeneca*, slip op. at 51-52.

II. THE COURT'S PLAIN-MEANING INTERPRETATION OF AWP DOES NOT DECIDE ANY OF THE ELEMENTS OF DOJ'S CAUSES OF ACTION.

Relying principally on *United States vs. Lachman*, 387 F.3d 42, 54-55 (1st Cir. 2004) – a non-FCA case – DOJ contends the Court's plain-meaning interpretation of AWP in Medicare law entitles it to summary judgment on *scienter*, falsity, causation, materiality, and what it calls a "government knowledge"/"government approval" defense. DOJ is wrong for a host of reasons.

First, DOJ's approach is merely a thinly-veiled attempt to avoid the issue of expectations and to impose *per se* liability. But, as the First Circuit noted, the Court "reject[ed] plaintiffs' position that . . . any spread between AWP and actual acquisition cost was per se unlawful." *Astra-Zeneca*, slip op. at 52, n.19. That officials fully expected mega-spreads on generic drugs (including the Subject Drugs) is indisputably relevant to whether the prices at issue were false. *Lachman* did not (as DOJ would have this Court do) determine that statements were false, while ignoring extensive evidence that the alleged targets of those statements never expected them to mean what DOJ now contends. To decide if Defendants committed fraud, the fact-finder must analyze Defendants' conduct on a drug-by-drug, state-by-state basis in light of applicable factors, including industry practice and expectations, how spreads developed, how spreads were used to achieve government payors' policy objectives, and the alleged marketing conduct.

Second, the Court's interpretation of AWP applies to Medicare, not Medicaid. Because DOJ has made no attempt to parse the meaning of "AWP" in the various state plans, summary

judgment cannot be entered on Medicaid claims. In fact, most states defined AWP in reference to compendia prices, or made clear that compendia prices will be used; the CMS officials who approved state plans understood "AWP" in those plans referred to compendia AWP. (C. SOAF ¶¶ 37; Mstr. Dkt. No. 6189 ¶ 51(g), (k).)[3] The discount from *compendia* AWP, such as AWP – 10%, was set after extensive "negotiation" between states and providers, with both CMS and states knowing full well that AWP-based payments provided a substantial percentage (but low dollar) margin on ingredient cost for generics. (C. Mem. at 6-11; C. SOAF ¶¶ 38-39, 43, 58-67.)

Third, *Lachman* targeted solely statutory and regulatory interpretation. It says nothing about the proper evidentiary analysis under the FCA, which requires consideration of the agency's understanding, knowledge, and policy irrespective of whether it is memorialized in the Federal Register. There is no such FCA case that truncates evidence in the fashion suggested by DOJ. For example, the FCA's *scienter* requirements necessitate consideration of whether a defendant's understandings are unreasonable when compared to an agency's implementation of a regulation; nothing in *Lachman* precludes this.[4] Rather, *Lachman* itself recognized that, "[w]hen the agency itself issues contradictory or misleading public interpretations of a regulation, there may be sufficient confusion for a regulated party to justifiably claim a deprivation of fair notice." 387 F.3d at 57. Indeed, in a subsequent appeal in *Lachman*, the court noted that non-public, informal agency interpretations consistent with defendant's understanding of a regulation "might have been of some use to bolster a good-faith defense." 521 F.3d 12, 18-19 (1st Cir. 2008).

[3] This does not mean states actually used (or had to use) compendia AWPs to set payment levels for generics. Knowing full well that compendia AWPs were not a reliable indicator of acquisition cost, many states established (and all states could have established) MACs for generics. (C. SOAF ¶¶ 79-86.) Moreover, many of the Subject Drugs were (or should have been) paid on the basis of a FUL. (*Id.* ¶¶ 87-89.)

[4] *See United States v. Prabhu*, 442 F.Supp.2d 1008, 1029 (D. Nev. 2006) (defendant does not "'knowingly' submit a 'false' claim when its conduct is consistent with a reasonable interpretation of ambiguous regulatory guidance").

Here, the Court's own expert found that "inconsistent and ambiguous information exists even currently regarding what type of price AWP measures," and that "[t]he continuing confusion is real and understandable." *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 285 (D. Mass. 2006); *accord Astra-Zeneca*, slip op. at 26 ("the precise meaning of 'average wholesale price' was unsettled"). State and federal officials overwhelmingly shared Defendants' understanding that "AWP" in statutes and regulations referred to undiscounted list prices that, for generics, were not constantly updated to reflect ever-changing market prices. (C. Mem. at 2-3, 8-9, 11-13; C. SOAF ¶¶ 1-3, 9, 11, 13, 37, 95-96, 98-102, 104; Mstr. Dkt. 6189 ¶ 51.) Given this industry understanding and the ambiguity and unsettled nature of AWP, a fact-finder could reasonably conclude that Defendants did not knowingly report false prices. (C. Mem. at 24-27, 31-33.)

Finally, the vast interpretive evidence here is nothing like the non-public, informal statements the court declined to consider in *Lachman*. Of particular note, the preamble to the 1991 Medicare regulation *specifically states* that CMS is adopting a "methodology for payment of drugs" that "will base payment on the lower of estimated acquisition cost or the *published* wholesale price of the drug." (C. SOAF ¶¶ 94-96) (emphasis added). Other evidence includes statements by the HHS Secretary to Congress (*id.* ¶¶ 100), language in numerous OIG reports (and CMS's responses) (*id.* ¶ (3(c), (e)-(f), (i)-(j)), CMS's instructions to Medicare carriers (*id.* ¶¶ 98, 102, 107), and the undisputed fact that, to this day, CMS interprets Congress's instruction to pay "AWP" to mean compendia AWPs (*id.* ¶¶ 129-33)[5]

[5] Although it is not necessary to reach this issue in adjudicating DOJ's motions, it should be noted that the Court's prior determination that AWP was not a term of art – a determination necessarily based on the evidence – was issued before the extensive testimony of state and federal officials given in these cases. (As the Court may recall, the Government asserted the *Touhy* regulations to prevent testimony from federal officials in Track 1.) Defendants respectfully submit that the evidence taken in these cases plainly shows – at least as to state and federal officials – that AWP was understood to refer to compendia AWPs, even though those prices (particularly for

III. THERE ARE DISPUTED FACTS ON WHETHER THE PROGRAMS KNOWINGLY PAID THE VERY MARGINS DOJ SEEKS AS DAMAGES.

Defendants have set forth extensive evidence showing Medicare and Medicaid knowingly paid margins (including so-called "mega-spreads") on the generic drugs at issue to achieve policy goals. (C. Mem. at 6-11; C. SOAF ¶¶ 38-39, 43-44, 58-67.) This evidence shows the programs used compendia AWPs despite knowing full well that this could result in paying margins on ingredient cost. (*Id.*) As CMS itself stated in response to OIG's draft report on the DOJ AWPs, there can be no "overpayment" if states "authorized" payments based on "inflated AWPs." (C. SOAF ¶ 72.) Accordingly, the evidence precludes summary judgment for DOJ on whether Defendants caused the payment of false claims.

DOJ's argument on what constitutes acquiescence in these cases is legally unsupported and nonsensical, and offers no response to the legal authorities cited by Defendants. (C. Mem. at 21-23.) The relevant question in these civil cases (which seek damages relating to the payment of margins) is not, as DOJ contends, whether the Government expressly approved of each Defendants' pricing, but whether the Government acquiesced in paying margins on drug reimbursement. Summary judgment cannot be granted in light of evidence such as that from CMS's Deidre Duzor, who admitted that "[w]e knew that for generic drugs that AWP minus was

(continued…)

generics) did not reflect prices actually paid by providers. (C. Mem. at 2-3, 8-9, 11-13; C. SOAF ¶¶ 1-3, 9, 11, 13, 37, 95-96, 98-102, 104; Mstr. Dkt. 6189 ¶¶ 51, 60.)

On this point, the testimony DOJ cites from CMS's Kathleen Buto, Don Thompson, and Tom Gustafson is of no help to DOJ. Buto clearly testified that the "national average wholesale price" language in the Medicare 1991 rule was meant to refer to "the average wholesale price as published in Red Book or similar price listings," not to actual market prices. (C. SOAF ¶ 104(e).) Thompson, CMS's 30(b)(6) witness, refused to provide substantive answers on how CMS interpreted AWP, instead merely reciting that any agency interpretation would be "contained in the rulemaking record." (*Id.* ¶ 105.) He admitted that the agency's interpretation of AWP is reflected in the Federal Register and CMS's Program Memoranda to carriers, both of which show CMS interpreted AWP to mean compendia AWP. (*Id.* ¶¶ 95-96, 107-08.) Finally, the Gustafson testimony merely confirms that it was "well-known" that the agency "interpreted" AWP to mean "average wholesale price in the Red Book." (Reply at 6.)

a generous payment based upon the IG's findings." (C. SOAF ¶ 62.)[6]

The remainder of DOJ's arguments provide nothing more than a place marker for factual disputes that the jury must resolve. For example, to support its claim that CMS had no cross-subsidization policy, DOJ curiously points to the testimony of Kathleen Buto. (Reply at 11.) But Buto candidly admitted: "[T]he government doesn't like to pay for some things under one mechanism that was intended for one use and sort of overpay there in order to compensate for other costs. In reality it happens." (C. SOAF ¶ 134.) Likewise, although former CMS Administrator Scully believed (as others may believe) that using compendia AWPs to cross-subsidize was "stupid policy," he – and CMS itself in the Federal Register and in response OIG reports – admitted it was, in fact, the reality. (*Id.* ¶¶ 104(c), 136-37, 148-49.) Indeed, cross-subsidization explains why Congress increased dispensing fees for inhalation drugs from $5 to $57 (later adjusted to $33) when Medicare moved to ASP. It is also why, in Scully's words, Congress chose to "freeze . . . some level of cross-subsidy" for infusion drugs by maintaining the AWP methodology even today for those products. (*Id.* ¶¶ 142-49.)

The evidence cited by DOJ from state officials shows, at best, the existence of more factual disputes. DOJ cites testimony from a DOJ-prepared Illinois 30(b)(6) witness to argue that the state had no policy of cross-subsidization. But an unbiased affidavit from an Illinois official asserts the state *did* have such a policy. (*Id.* ¶ 45(e)). And a 1993 GAO report relating to Illinois and Maryland stated: "HCFA and state Medicaid officials agreed that pharmacies must often use excess Medicaid reimbursements to cover their dispensing costs." (*Id.* ¶ 44.)

At trial, Defendants will present evidence of cross-subsidization and of other reasons why

[6] DOJ also constructs and tries to fell various straw-man arguments, like "defendants contend . . . [they] could report whatever they wished as AWP." (Reply at 2-3.) Defendants, of course, have never made such a contention, and they certainly did not report "whatever they wished." The spreads here were not "created" to cheat Medicare or Medicaid, but rather developed as a result of the competitive generic marketplace (where prices decline) and adherence to industry standards. (*See* Abt. Opp. at 5-6; Dey Opp. at 9-10; Mstr. Dkt. 6178 at 38-39.)

Medicaid programs intentionally paid margins on ingredient cost from dozens of states. (*Id.* ¶¶ 44-57, 59(a)-(b), (d)-(f), 71-75.) For example, thanks to a recent discovery ruling, Defendants will present Georgia documents in which a key Medicaid employee expressed reservations about AWP litigation generally, including the fact that the state "and other payors have attempted to compensate for 'overpaying' on the ingredient cost side by paying a dispensing fee that is lower than the surveyed actual cost to dispense." (*See* Exs. A-E, attached to Torborg Decl.) These candid statements underscore why many state officials have not supported this litigation.

On these facts, DOJ had no business seeking summary judgment against any Defendant. What follows are additional, case-specific reasons why DOJ's motions should be denied.

ABBOTT

Abbott and DOJ agree that a trial is inevitable in the Abbott case. Initially, DOJ moved for summary judgment only as to Medicaid. (Dkt. No. 318 at 10 ("The United States is moving for partial summary judgment on elements of its FCA Medicaid claims.").) Because DOJ has offered nothing more than a plain-meaning interpretation of AWP that does not apply to Medicaid (*see supra* at 3-4), it has no basis for summary judgment on any of its claims.

Moreover, Abbott has shown that state and federal officials knew throughout the claims period that the large volume infusion solutions at issue here (sterile water, dextrose, and saline) sold at prices more than 90% below AWP (a 900% spread), and that they expected discounts for vancomycin of 75-80% below AWP (a 400% spread). (Abt. Opp. at 15-16; AF ¶¶ 83-89.) The Government also received, throughout the claims period, AMPs for the Subject Drugs showing that sales prices were far below compendia AWPs. (Abt. Opp. at 12-13.) And there can be no dispute that the Government was aware of the spreads at issue here since at least June 1995, when Ven-A-Care filed its *qui tam* complaint. Abbott also presented evidence that government

payors expected, and indeed fully intended, to pay substantial premiums to providers of infusion drugs in order to compensate for inadequate (and indeed sometimes non-existent) service fees. (*See* Abt. Opp. at 17-19; AF ¶¶ 90-113; C. SOAF ¶¶ 70-75.) This evidence alone defeats summary judgment entirely.

In reply, DOJ does not deny these facts, but instead argues that other facts show government payors did *not* expect or acquiesce in spreads like those for the Subject Drugs. (Reply at 7-9.) For instance, DOJ reviews selected testimony from two Abbott experts, suggesting these snippets are inconsistent with the experts' overall opinions that government payors understood the true nature of AWP and made informed policy decisions to pay spreads to providers. (*Id.* at 7-8.) DOJ is wrong on all counts, as Abbott will prove at trial. At summary judgment, however, DOJ's arguments present, at most, disputed issues of fact which must be viewed in the light most favorable to Abbott.

With respect to the pricing of the Subject Drugs, Abbott's opposition showed that, among other things, (i) List Prices were controlled by a business unit that had no concern for AWP; (ii) List Prices were set without any intention to influence government payments; (iii) Abbott did not report an AWP to the compendia; (iv) Abbott accurately reported List Prices because that is what the compendia requested; (v) Abbott did not understand that AWP was meant to reflect an actual average price, or that Abbott had any obligation to report such a price to the compendia; (vi) the spread on the Subject Drugs was unintentional and was corrected by Abbott when it was discovered; and (vii) Abbott did not market the spread. (Abt. Opp. at 1-6.) Once again, DOJ does not contest these facts, nor explain how these issues can be resolved as a matter of law. Instead, the Government trots out various facts that allegedly conflict with those cited by Abbott – evidence that in DOJ's view shows that at least *some* people within Abbott understood the

relationship of List Prices to AWP; or that at least *one* pricing decision in 1995 for *one* of the Subject Drugs was influenced by AWP; or that, contrary to the instructions given to Abbott, perhaps the compendia did *not* want manufacturers to report their highest undiscounted prices. (Reply at 2-7.) The alleged "facts" trumpeted by DOJ (which are uniformly overstated, if not outright false) do not establish Abbott's *scienter*, or any other element of liability. They are, at most, facts DOJ will attempt to introduce at trial to counter Abbott's proofs. In light of these disputed issues of fact, summary judgment must be denied.

DEY

DOJ's motion for partial summary judgment against Dey should be denied in its entirety. Both Dey and DOJ agree that a trial is inevitable in the Dey case. However, DOJ's claim that summary judgment in its favor would clarify and narrow the issues to be tried is simply unfounded; any such findings would only add to the complexity of an already complicated trial. Even if DOJ prevailed on its cross motion, a trial would still be necessary on the following:

- All Medicaid claims paid based on Dey's WACs for all of Dey's Subject Drugs (except for claims paid based on WACs published in one pricing compendia from June 1, 1995 through December 31, 1997 for unit dose albuterol sulfate, *see* Dey Opp. at 22-42);
- All Medicare claims for all of Dey's Subject Drugs (except for ipratropium bromide claims processed by a single DMERC, CIGNA from April 1, 1997 through September 30, 2001); and
- Dey's affirmative defenses.[7]

Any specific findings made at the summary judgment stage cannot be extended to encompass the remaining time periods, drugs, and DMERCs that will remain for trial. Moreover, DOJ has not even attempted to rebut Dey's argument that it could not have knowingly caused the submission of false claims by reporting AWPs at the same time it reported declining WACs and submitted

[7] Although DOJ initially moved for summary judgment on Dey's affirmative defenses, it failed to set forth any evidence to demonstrate the absence of a material question of fact, and DOJ did not even attempt to rebut the legal arguments put forth by Defendants against summary judgment on affirmative defenses.

AMPs to CMS. Even had DOJ set forth facts sufficient to prevail on any of the points it has moved on, which – as discussed below – it has not, the piecemeal adjudication it seeks will leave most key issues for trial and only cause unnecessary confusion, time and expense.

In failing to rebut the argument concerning Dey's publicly available WACs, DOJ effectively concedes that issues of fact exist as to falsity, *scienter*, and causation for Dey's AWPs. As for Dey's AMPs, FSS prices, and price notification letters, DOJ does not dispute that, taken together with the OIG reports on Dey's drugs, they were more than sufficient to apprise CMS and state Medicaid agencies of the prices paid in the marketplace for Dey's drugs. Rather DOJ argues that, because of the complexities of its chosen reimbursement methodologies, there was little it could do with this information. That also is an issue of fact since Dey's Subject Drugs were subject to MACs and FULs for much of the relevant time frame, showing that CMS and the states could and did adjust reimbursement for specific drugs when they wanted to. DOJ's arguments concerning Dey's "reliance" on the government's "approval" likewise miss the mark as there is simply no requirement that, to rebut a showing of falsity, Dey must prove explicit government "approval," much less Dey's "reliance" on that approval. (C. Memo. at 23.) All of this is a matter for the jury and cannot be decided as a matter of law.

ROXANE

DOJ's reply ignores the multitude of cases cited by Roxane establishing that there can be no falsity or *scienter* when there is statutory or regulatory ambiguity and a party's interpretation of its duties is not "beyond gross negligence." Instead, DOJ attempts to convert the FCA into a strict liability statute by disregarding the controlling case law establishing that liability under the FCA cannot attach when a defendant has not objectively violated a "law, regulation, or other source" demonstrating that a claim is "false." (Rox. Opp. at 3-11.) DOJ does not attempt to

point to *any* predicate statute, regulation, or contract that Roxane objectively violated, much less try to establish with undisputed evidence that Roxane's understanding of AWPs – which was consistent with an entire industry's understanding – was "beyond gross negligence" when compared to a non-existent objective statutory or regulatory duty.

DOJ also ignores the voluminous factual record that demonstrates, at a minimum, that there was ambiguity about what reported AWPs were intended to be. DOJ certainly does not proffer undisputed evidence to establish as a matter of law that Roxane's practices and understanding with respect to AWPs meet the high threshold for establishing either falsity or *scienter* under the FCA. Instead, the entirety of DOJ's "evidence" with respect to Roxane continues to consist of nothing more than its *ipse dixit* conclusion that if Roxane's published AWPs were something other than a calculated mathematical average, *per se* liability attaches under the quasi-criminal FCA statute. This, of course, is not the law. (Rox. Opp. at 3-11.)

DOJ also continues to ignore Roxane's testimony that it never intended its AWPs to be used as actual averages of customer prices – or represented that they were – because that was not the industry meaning of AWP. (Rox. Opp. at 7-10.) Moreover, DOJ has *no* response to the undisputed fact that Roxane sent its "true" discounted prices in the form of AMPs *directly* to HCFA/CMS *every* quarter for *every* NDC at issue. For instance, DOJ does not dispute that Roxane's AMPs for ipratropium bromide, the drug with the largest amount of purported damages in this case, were very close to the average prices calculated by DOJ's expert. (*Id.* at 9.) This nullifies DOJ's predicate argument that Roxane's scienter is demonstrated by the "fact" that its "true" prices were "hidden" from HCFA/CMS. All of this evidence demonstrates that DOJ has no basis to prevail on its far-reaching motion for summary judgment against Roxane: numerous material facts remain very much in dispute.

Dated: October 5, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, David S. Torborg, an attorney, hereby certify that I caused a true and correct copy of the foregoing to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 5th day of October, 2009.

/s/ David S. Torborg
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